UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

	:	**Case No. 1:01-CV-9000**
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IN RE: SULZER HIP PROSTHESIS AND KNEE PROSTHESIS LIABILITY LITIGATION	:	**(MDL Docket No. 1401)**
	:	**JUDGE O'MALLEY**
THIS DOCUMENT RELATES TO:	:	
Howard v. Sulzer Orthopedics, Inc., 1:03CV9006	:	**MEMORANDUM & ORDER**
Burgess v. Sulzer Orthopedics, Inc., 1:04CV9005	:	

This opinion discusses three cases that have been transferred to this Court as related to Multi-District Litigation ("MDL") No. 1401, known as *In re: Sulzer Orthopedics Inc. Hip Prosthesis and Knee Prosthesis Products Liability Litigation*.[1] The three cases are: (1) *Moore v. Sulzer Orthopedics, Inc.*, case no. 02-CV-9116; (2) *Howard v. Sulzer Orthopedics, Inc.*, case no. 03-CV-9006; and (3) *Burgess v. Sulzer Orthopedics, Inc.*, case no. 04-CV-9005.

The Court earlier issued an opinion granting summary judgment to the defendants in the *Moore* case. *Moore v. Sulzer Orthopedics, Inc.*, 337 F. Supp. 2d 1002 (N.D. Ohio 2004). Sulzer now seeks dismissal of the *Howard* and *Burgess* cases, as well. For the reasons stated below, Sulzer's request is **GRANTED in part**; specifically, all of the claims asserted in *Howard* and *Burgess* are **DISMISSED**, except for their claims of negligence per se.

[1] Sulzer Orthopedics, Inc. was later renamed Centerpulse Orthopedics, Inc., and then purchased by Zimmer Holdings, Inc. The Court refers to the defendant as "Sulzer."

I. History

The *Moore*, *Howard*, and *Burgess* cases share the following factual and procedural similarities. Each plaintiff alleges in his complaint that he underwent knee replacement surgery and received an orthopedic knee implant manufactured by Sulzer known as the "Natural Knee II Tibial Baseplate" (referred to below as the "NK-II"). The NK-II is one component of a system used for complete knee replacements. Each plaintiff further alleges that: (1) his implant was coated with a lubricant during the manufacturing process; (2) Sulzer failed to remove this lubricant completely before the implant was placed in his body; (3) the lubricant then caused the implant to bond improperly to his bones; and (4) he ultimately had to have the implant removed and replaced. Each plaintiff asserts various claims under their applicable state law, such as strict liability for defective design and manufacture, negligence for defective design and manufacture, and failure to warn.

Further, the plaintiff in each case originally filed his lawsuit in a court other this one. Specifically, after Moore filed his case in Florida state court, Sulzer removed the action to the United States District Court for the Middle District of Florida. Howard filed his case in the United States District Court for the Northern District of Oklahoma. And, after Burgess filed his case in Arkansas state court, Sulzer removed the action to the United States District Court for the Western District of Arkansas. Each of the three cases was then transferred to this Court as related to MDL No. 1401.

Unlike *Howard* and *Burgess*, however, the *Moore* case has progressed to a resolution. In *Moore*, Sulzer moved for summary judgment on the ground that all of Moore's claims were preempted by federal law. The essence of Sulzer's argument was as follows:

(1) Sulzer applied successfully to the FDA for premarket approval ("PMA") of its NK-II, pursuant to the Medical Devices Amendment ("MDA") to the Food, Drug and Cosmetic Act, 21 U.S.C. §360c *et seq.* The FDA's PMA process involves rigorous review of the design,

manufacturing methods, quality control procedures, clinical investigations, and labeling and marketing of the medical device;

(2) the MDA contains an express preemption clause that precludes a State from "establish[ing] or continu[ing] in effect with respect to [any medical device examined by the FDA in the PMA process] any requirement . . . which is different from, or in addition to, any requirement applicable . . . to the device" under the MDA itself, 21 U.S.C. §360k(a); and

(3) the state law causes of action stated by Moore would all work to impose requirements on the NK-II that were "different from, or in addition to," the FDA requirements, and were thus preempted.

Moore's response to Sulzer's syllogism began by observing that there is a split of authority amongst the federal appellate courts regarding the extent of MDA preemption.[2] For example, in *Goodlin v. Medtronic, Inc.*, 167 F.3d 1367, 1371 (11th Cir. 1999), the Eleventh Circuit Court of Appeals concluded that common law duties imposed by state tort law are *not* "requirement[s] that are different from, or in addition to, any requirement applicable . . . to the device" under the MDA. Accordingly, the *Goodlin* court allowed a plaintiff to pursue claims that his FDA-approved pacemaker was defective. In contrast, in *Kemp v. Medtronic, Inc.*, 231 F.3d 216, 221 (6th Cir. 2000), *cert. denied*, 534 U.S. 818 (2001), the Sixth Circuit Court of Appeals rejected the *Goodlin* analysis, concluding that the plaintiff's state-law claims – which related to the same FDA-approved pacemaker discussed in *Goodlin* – were preempted.

Moore argued that this Court should apply the law from the Eleventh Circuit Court of Appeals (as set out in *Goodlin*) instead of the law from the Sixth Circuit Court of Appeals (as set out in *Kemp*), even though this Court is within the Sixth Circuit. Noting that his case had been

[2] This split derives from the fractured plurality opinion delivered by the Supreme Court when it confronted the scope of the MDA preemption provision in *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996). *See Moore*, 337 F. Supp. 2d at 1007-09 (discussing *Lohr* and the split in federal appellate authority).

transferred to this MDL Court from the Eleventh Circuit, Moore argued that "the transferee forum must apply the law of the transferor court." *Moore*, 337 F. Supp. 2d at 1009. This Court rejected Moore's argument, however, concluding: "this Court's preemption analysis addresses a question of *federal* law, and this Court is required to apply the Sixth Circuit's interpretations of federal law to any case that is transferred to it." *Id.* at 1011 (footnote omitted, emphasis in original). Accordingly, the Court granted Sulzer's motion for summary judgment and dismissed Moore's case. Moore did not appeal.

In light of the Court's conclusion in *Moore*, Sulzer moved the Court to issue an Order requiring all similarly-situated plaintiffs – including Howard and Burgess[3] – to show cause why their cases should not also be dismissed. The Court acquiesced to this request, and the parties have submitted briefs regarding whether, and the extent to which, the Court's reasoning in *Moore* should apply to *Howard* and *Burgess*.

II. Medical Devices and Preemption.

The Court picks up where it left off in its *Moore* opinion, the entirety of which is incorporated herein by reference.[4]

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[3] The Court's Order also applied to three other similarly-situated plaintiffs, whose cases had been transferred to this MDL: *McDonough v. Sulzer Orthopedics, Inc.*, case no. 04-CV-9002; *Hulse v. Sulzer Orthopedics, Inc.*, case no. 03-CV-9009; and *Boyd v. Sulzer Orthopedics, Inc.*, case no. 03-CV-9003. These three cases have already been dismissed, however, either because the plaintiffs stipulated to dismissal or did not respond to the Court's show cause order.

[4] Rather than setting out, again, the history of this MDL and the Court's analysis of federal preemption in the context of the MDA, the Court simply incorporates in full the reasoning and analysis set out in *Moore*, 337 F. Supp. 2d 1002. Should any party later wish to appeal this Order, the Court makes clear here that *Moore* must be included as an addendum to this Order and made a part of the appellate record.

Critically, in *Moore*, the plaintiff advanced only one argument in response to Sulzer's summary judgment motion: that the law of the Sixth Circuit, as set out in *Kemp*, was not applicable; and that, instead, the Court should apply the law of the Eleventh Circuit, as set out in *Goodlin*. Because this argument failed, Sulzer's motion carried. But this Court noted that other arguments not advanced by Moore might yield different results:

> Conceivably, the Court's easy conclusion that it must apply the *Kemp* preemption analysis, and not the *Goodlin* preemption analysis, would not be dispositive of the pending motion. As the *Kemp* court noted, "a claim premised on the violation of FDA requirements established for a Class III device through the PMA process is not automatically preempted." *Kemp*, 231 F.3d at 230. Moore could conceivably argue, for example, that Sulzer was negligent in its manufacture of the NK-II he received because Sulzer completely failed to undertake a manufacturing step – say, a product rinse, or a quality control inspection – that is "required" by the FDA. Alternatively, Moore could contend that Sulzer *added* a manufacturing step or process that was in addition to and materially deviated from the manufacturing processes approved by the FDA. But Moore does not offer any such argument or point to any such fact.

Moore, 337 F. Supp. 2d at 1011.

Howard and Burgess offer two arguments why the reasoning in *Moore* should not control their case. First, Howard offers additional support for the argument that *Kemp* should not control, and this Court should apply the law of the transferor court. Second, relying in part on the language quoted above from *Moore*, Howard and Burgess both argue that, even if *Kemp* does apply, at least some of their claims survive the doctrine of federal preemption. The Court examines these arguments below.

A. Applicable Law.

Like the Eleventh Circuit Court of Appeals in *Goodlin*, the Tenth Circuit has suggested that

certain common law duties imposed by state tort law are *not* "requirement[s] that are different from, or in addition to, any requirement applicable . . . to the device" under the MDA. *See Oja v. Howmedica, Inc.*, 111 F.3d 782, 789 (10th Cir. 1997) ("the duties imposed by Oja's negligent failure to warn claim do not constitute positive enactments of state law sufficient to constitute a state requirement developed 'with respect to' a medical device").[5] Because Howard filed his case in the Tenth Circuit, he seeks application of the law as set out in *Oja* instead of the Sixth Circuit law set out in *Kemp*.[6] Howard offers a number of cogent arguments that Moore did not raise to support the proposition that the law of the transferor court should apply.[7]

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[5] In fact, it is not completely accurate to state that the *Oja* and *Goodlin* courts reached the same conclusion. The Eleventh Circuit was alone among the Courts of Appeals when it ruled in *Goodlin* that §360k(a) does not preempt common law claims involving PMA-approved devices. While the Tenth Circuit had earlier ruled in *Oja* that the MDA did not preempt common law tort claims against a medical device manufacturer, the device at issue in *Oja* did not undergo the §360e(c) PMA analysis; rather it underwent the far less rigorous Investigative Device Exception (IDE) process. Even assuming that *Oja* stands for the proposition that the Tenth Circuit would adopt fully the *Goodlin* preemption analysis, however, the Court concludes it is bound to follow *Kemp* and not *Oja*.

[6] Burgess does not make a similar argument because the law of the Eighth Circuit, which would control if this Court were to adopt the rule that "the law of the transferor court applies," is consonant with the law of the Sixth Circuit. *See Brooks v. Howmedica, Inc.*, 273 F.3d 785, 796 (8th Cir. 2001), *cert. denied*, 535 U.S. 1056 (2002) ("The failure to warn claim asserted by Brooks would interfere or conflict with the specific federal requirements imposed during the regulation of Simplex. A jury finding of negligent failure to warn would be premised on the fact that the label for Simplex was not written in a particular way or did not contain certain information. This would be equivalent to a state regulation imposing specific label requirements.").

[7] The Court finds especially provocative – but ultimately not persuasive – the following two-pronged argument, which Moore did not raise but Howard did: (1) the law of the transferor court applies when transfers are made pursuant to 28 U.S.C. §1404(a), because a defendant should not "get a change of law as a bonus for a change of venue," *Van Dusen v. Barrack*, 376 U.S. 612, 635 (1964), and the same anti-forum-shopping policy should adhere in cases where the transfer is made in an MDL, pursuant to 28 U.S.C. §1407; and (2) if anything, the reasoning behind the *Van Dusen* rule applies even more strongly in the MDL context, given that the transferee court would often have no independent basis to exercise personal jurisdiction over the transferred MDL plaintiff.

For the reasons stated in *Moore*, however, the Court remains unpersuaded. First, even if this Court were free to choose between the Tenth and Sixth Circuit's analyses of the law of MDA preemption, the Court would choose the latter. *See Moore*, 337 F. Supp. 2d at 1011 n.7 ("Not only does the Court find the *Kemp* analysis more consistent with the *Lohr* plurality than the *Goodlin* analysis, but under *Goodlin*, the preemption provision of the MDA becomes virtually meaningless – a result Congress cannot have intended.").

Second, the Sixth Circuit Court of Appeals has directed this Court to use the law of this Circuit in precisely these circumstances. In *In re Cardizem CD Antitrust Litig.*, 332 F.3d 896 (6th Cir. 2003), *cert. denied*, 543 U.S. 939 (2004), the appellate court observed that, when examining questions of federal law "in a federal multidistrict litigation[,] there is a preference for applying the law of the transferee district." *Id.* at 912 n.17. As this Court noted in *Moore*, the Sixth Circuit added the caveat that this rule was less clear when the law of the transferee court is "'unique' to [that] particular circuit and arguably divergent from the predominant interpretation of a federal law." *Id.; Moore*, 337 F. Supp. 2d at 1010. Howard seeks the shelter of this caveat, but the requisite conditions are not present. In *Moore*, the undersigned wrote:

> MDA preemption analysis set out in *Kemp* is not unique to the Sixth Circuit, nor is it divergent from the predominant interpretation. *See Brooks v. Howmedica, Inc.*, 273 F.3d 785, 795 (8th Cir. 2001) ("[m]ost courts of appeal have interpreted *Lohr* to mean that the MDA preempts common law claims to the extent that they interfere or conflict with specific federal requirements") (citing *Kemp* and other cases). Thus, it is clear that this Court must apply the *Kemp* preemption analysis, and not the *Goodlin* analysis.

Id. at 1010. Since then, two additional Courts of appeal have joined the majority view stated in *Kemp*, making it even more clear that *Oja* and *Goodlin* are the divergent cases. *See Riegel v. Medtronic, Inc.*, 451 F.3d 104, 106 (2nd Cir. 2006), *petition for cert. filed*, 75 U.S.L.W. 3065 (Aug.

3, 2006) ("[w]e now join this growing consensus and hold that tort claims that allege liability as to a PMA-approved medical device, notwithstanding that device's adherence to the standards upon which it obtained premarket approval from the FDA, are preempted by Section 360k(a)"); *Horn v. Thoratec Corp.*, 376 F.3d 163 (3rd Cir. 2004) ("we, together with our sister Courts of Appeal who have read *Lohr* in the same fashion as we have, and together with the FDA's current position, hold that Horn's claims are preempted by § 360k(a)") (footnote omitted). *See also Gomez v. St. Jude Medical Diag Division, Inc.*, 442 F.3d 919 (5th Cir. 2006) (reaffirming the Fifth Circuit's adherence to the majority view, first set out in *Martin v. Medtronic, Inc.*, 254 F.3d 573 (5th Cir. 2001)); *Cupek v. Medtronic, Inc.*, 405 F.3d 421 (6th Cir. 2005) (reaffirming *Kemp*); *McMullen v. Medtronic, Inc.*, 421 F.3d 482 (7th Cir. 2005) (reaffirming the Seventh Circuit's adherence to the majority view, first set out in *Mitchell v. Collagen Corp.*, 126 F.3d 902 (7th Cir. 1997)).

Simply, Howard seeks application of a minority view on the scope of MDA federal preemption, and *Cardizem* holds that this MDL court must apply the majority view if it has been adopted by the Sixth Circuit. Because *Kemp* shares the majority view, this Court will apply the law of the Sixth Circuit to Howard's case, not the law of the Tenth Circuit.

B. Preempted Claims.

Howard and Burgess assert a slew of claims against Sulzer, including: (1) strict liability for design defect; (2) strict liability for manufacturing defect; (3) strict liability for defective marketing and/or failure to warn; (4) negligence; (5) breach of implied warranty; (6) breach of express warranty; (7) deceit by concealment; (8) negligence per se; (9) medical monitoring; (10) fraud; and (11) loss of consortium. This Court must determine whether each of these claims is preempted by

§360k(a) of the MDA. Fortunately, this obligation is made easier because seven different Courts of Appeals, including the Sixth Circuit in *Kemp* and *Cupek*, have undertaken the same task, examining the preemptive effect of the MDA on a great variety of state law claims – including virtually all of the sorts of claims advanced by Howard and Burgess. Taken together, these cases reveal that §360k(a) preempts almost every type of state law claim that seeks to hold a defendant liable for a PMA-approved medical device; the only exception is a claim that the medical device failed to conform with the FDA requirements prescribed by the PMA.[8] The Court reviews these cases briefly below.

As an initial matter, to determine whether a particular claim is preempted, all of the appellate courts "require a district court to look through the general duties imposed by the state-law causes of action and consider the effect a successful lawsuit asserting those causes of action would have and determine whether they threaten the federal PMA process requirements." *Gomez*, 442 F.3d at 929-30. Unsurprisingly, the cases are unanimous in concluding that a state law claim of design defect is preempted. As the *Gomez* court recognized, "[t]o permit a jury to second-guess the [medical device's] design by applying the Louisiana statutory standard for unreasonably dangerous design would risk interference with the federally-approved design standards and criteria." *Id.* at 930. *See*

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[8] The cases that inform this Court's analysis, listed in order of Circuit Court, are: (**Second**) *Riegel v. Medtronic, Inc.*, 451 F.3d 104 (2nd Cir. 2006); (**Third**) *Horn v. Thoratec Corp.*, 376 F.3d 163 (3rd Cir. 2004); (**Fifth**) *Gomez v. St. Jude Medical Diag Division, Inc.*, 442 F.3d 919 (5th Cir. 2006); *Martin v. Medtronic, Inc.*, 254 F.3d 573 (5th Cir. 2001); (**Sixth**) *Kemp v. Medtronic, Inc.*, 231 F.3d 216 (6th Cir. 2000), *cert. denied*, 534 U.S. 818 (2001); *Cupek v. Medtronic, Inc.*, 405 F.3d 421 (6th Cir. 2005); (**Seventh**) *McMullen v. Medtronic, Inc.*, 421 F.3d 482 (7th Cir. 2005); *Mitchell v. Collagen Corp.*, 126 F.3d 902 (7th Cir. 1997); (**Eighth**) *Brooks v. Howmedica, Inc.*, 273 F.3d 785, 795 (8th Cir. 2001); (**Ninth**) *Papike v. Tambrands, Inc.*, 107 F.3d 737 (9th Cir. 1997). As noted above, the Court does not rely upon the Tenth Circuit's opinion on *Oja* or the Eleventh Circuit's opinion in *Goodlin*, because they do not adhere to the majority view.

also Horn, 376 F.3d at 176 (the "design defect claims . . . would require [the defendant] either to use an entirely different design . . . or to use different materials . . . or to place [a part] in a different position. * * * [The defendant] is prohibited, however, by the FDA's PMA approval order from making any such changes.").

Similarly, the cases are unanimous in concluding that a state law claim for failure to warn is preempted, in light of the fact that the PMA process includes FDA scrutiny of the warning labels that the manufacturer must supply with the medical device.[9] Quoting *Gomez* again:

> The FDA approved [defendant] Kendall's warnings and instructions for physicians contained in the Instructions for Use ("IFU") through the PMA process. That process required the FDA to approve clinical studies and evaluate the results, to specify the labeling requirements, and and approve the label that issued. The FDA also approved the "Patient Guide" used to provide information and warnings to patients, again through the PMA process. Kendall's training requirements were also subjected to, and approved in, the PMA process. To permit a jury to decide Gomez's claims that the information, warnings, and training material the FDA required and approved through the PMA process were inadequate under state law would displace the FDA's exclusive role and expertise in this area and risk imposing inconsistent obligations on Kendall. The district judge correctly found that Gomez's state-law claims that Kendall's labeling, warning, information, and training were inadequate or incomplete are preempted.

Gomez, 451 F.3d at 931.

The Sixth Circuit agrees entirely with the reasoning of *Gomez*: "Any claim, under state law, then, that Defendant failed to warn patients beyond warnings required by the FDA, or that Defendant failed to recall a product without first going through the PMA supplement process would constitute state requirements 'different from' or 'in addition to' the requirements of the federal PMA application and supplement process." *Cupek*, 405 F.3d at 424. *See also* Horn, 376 F.3d at 176

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[9] A PMA application "shall contain * * * specimens of the labeling proposed to be used for [the medical] device." 21 U.S.C. §360e(c)(1)(F). If the labeling is found to be "false or misleading in any particular," the application for approval must be denied. *Id.* §360e(d)(2)(D).

(holding that the plaintiff's "failure-to-warn claims" are preempted because they "would require [the defendant] to provide different warnings and instructions from those approved by the FDA"); *Martin*, 254 F.3d at 583 ("the PMA process imposed specific federal requirements as to labeling, manufacturing, and design for the purposes of preemption"); *Kemp*, 231 F.3d at 236 ("to the extent that plaintiff's claim is premised on the adequacy of the warnings reviewed and approved by the FDA, . . . the claim is . . . preempted"); *Brooks*, 273 F.3d at 796 ("The effect of a jury finding of negligent failure to warn would be that state law would require [the defendant] to change the label and package insert for [the medical device], but [the defendant] may not unilaterally make such changes under federal law"); *McMullen*, 421 F.3d at 488 ("A claim that a manufacturer failed to provide an adequate warning at the time of sale would be based on the assertion that the manufacturer should have provided a different warning than the one approved by the FDA. Such a state-law claim would impose a requirement that was different from, or in addition to, the applicable federal requirements and would be preempted.").[10]

The cases are also unanimous in decreeing a similar fate for claims for breach of implied warranty. As explained by the *Mitchell* court, "an implied warranty claim is based on the accepted standards of design and manufacture of the products. In the case of a product that has gone through the PMA process, these criteria are set by the FDA." *Mitchell*, 126 F.3rd at 915. Allowing a

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[10] Also preempted are claims premised on a "*post-sale* duty to warn," where the plaintiff alleges the defendant was required to provide *additional* warnings in light of later-received reports of injury to others caused by the same medical device. *McMullen*, 421 F.3d at 488 (emphasis in original). *See Cupek*, 405 F.3d at 422, 424-25 (concluding that the plaintiff's "'post-sale failure to warn' and post-sale 'failure-to-recall' claims" were preempted); *Gomez*, 442 F.3d at 931 ("Gomez's state-law claims related to [the defendant's] alleged failure to provide information obtained after the FDA approved the [medical device] risk the same interference with the federal regulatory scheme as her other claims and are preempted.").

plaintiff to pursue a breach of implied warranty claim would create an irreconcilable conflict: a "judgment for breach of implied warranty that rested on allegations about standards other than those permitted by the FDA would necessarily interfere with the PMA process and, indeed, supplant it." *Id.* Accordingly, claims for breach of implied warranty are preempted. *See also Riegel*, 451 F.3d at 121-22 (plaintiffs' claims "for strict liability, breach of implied warranty, and negligent design, testing, inspection, distribution, labeling, marketing, and sale would, if successful, impose state requirements that differed from, or added to, the PMA-approved standards for the [medical device]"); *Horn*, 376 F.3d at 168 (reaffirming MDA preemption of claims for "breach of implied warranty of merchantability and fitness for a particular purpose").

Indeed, it is the rare state-law claim that the above-cited federal appellate courts conclude is *not* preempted by §360k(a) of the MDA, and those rare examples are instructive. In *Martin*, two plaintiffs brought a variety of state-law claims against the manufacturer of their pacemaker, Medtronic, including "negligence, gross negligence, strict liability, breach of warranty, and violation of the Texas Deceptive Trade Practices Act." *Martin*, 254 F.3d at 575. The district court found all of the plaintiffs' claims were preempted, except one: the claim "that Medtronic had deviated from FDA requirements." *Id.* The *Martin* court affirmed this conclusion, reasoning that "common law duties that incorporate the PMA process, such as the general duty to take due care to comply with the PMA process in labeling or manufacturing, will never contain specific requirements that are additional to or different from federal requirements. Therefore, claims based on those duties are not preempted." *Id.* at 582 n.8 (citing *Lohr*, 518 U.S. at 495).

Put more simply: "state tort suits that allege, as the basis of their claim, that the approved FDA requirements have not been met are not preempted." *Id.* at 583. Other state law claims are.

Thus, the plaintiffs in *Martin* were permitted to pursue one claim: that Medtronic had not complied with the FDA-approved manufacturing process. After discovery was complete, however, the district court granted Medtronic's motion for summary judgment, "finding that [the plaintiffs] failed to produce evidence of alleged deviations" from FDA requirements, and the appellate court affirmed. *Id.* at 575.

The Sixth Circuit reached an identical conclusion in *Kemp*, where the plaintiffs brought "ten common law and statutory products liability claims under Ohio law" against defendant Medtronic. *Kemp*, 231 F.3d at 219. The district court found that "the MDA preempted plaintiffs' strict products liability claims for defective design, failure to warn, and nonconformance to representations, as well as their claims for negligent design, negligent failure to warn, breach of express and implied warranties, and fraudulent misrepresentation." *Id.* But the district court "did not find that the MDA totally preempted plaintiffs' claims, . . . [ruling] that any claims alleging the [medical device] deviated from FDA specifications were not preempted." *Id.* at 419-20.

As in *Martin*, this conclusion provided cold comfort to the plaintiffs, who then pursued their claim for "negligence per se" for failure to adhere to FDA requirements. The plaintiffs were unable to adduce evidence sufficient to support this claim, and suffered summary judgment. On appeal, the Sixth Circuit Court of Appeals agreed with the plaintiffs "that a claim premised on the violation of FDA requirements established for a [medical] device through the PMA process is not automatically preempted," *id.* at 230, but also agreed that summary judgment on the plaintiffs' negligence per se claim for lack of evidence was appropriate.[11]

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[11] The trial court and the Sixth Circuit Court of Appeals reached essentially the same conclusions again in *Cupek*.

Gomez presents a slight variation on this theme. In *Gomez*, the district court found that "federal law preempted [the plaintiff's] state-law claims for defective design, failure to warn, breach of express warranty, negligence in training and consent forms, and redhibition." *Gomez*, 442 F.3d at 927. The district court allowed the plaintiff to pursue, however, her claim that the defendant "fail[ed] to manufacture the [medical] device in accordance with FDA specifications." *Id.* at 926. The parties proceeded to trial and, after the close of evidence, the district court granted a Rule 50 motion for judgment as a matter of law. The appellate court affirmed the district court's conclusion that the defective manufacturing claim was not preempted: "The district judge properly limited Gomez's negligence claims to a claim that the [medical device] used in her surgery was defectively manufactured because it did not comply with the FDA-approved specifications." *Id.* at 933. Unlike in *Martin* and *Kemp*, however, the *Gomez* court reversed the trial court's order granting the Rule 50 motion, concluding that the plaintiff had "introduced sufficient evidence of defect and causation to allow the jury to resolve her manufacturing defect claim." *Id.* at 938. Specifically, the plaintiff had adduced evidence that the manufacturer did not comply with FDA standards requiring disposal of manufacturing lots with a nonconformance percentage in excess of 0.01%. *Id.* at 935-36.

Martin, *Kemp*, and *Gomez* stand for the proposition that virtually all state law claims seeking to hold a defendant liable for injuries caused by an FDA-approved medical device are preempted, except for a claim that the medical device failed to conform with the PMA requirements prescribed by the FDA. Kindred conclusions are also stated in the other cases on point. *See Riegel*, 451 F3d at 106 ("With regard to the plaintiffs' remaining claim for negligent manufacturing – which premised liability on the theory that the particular [medical device] deployed during plaintiff-appellant Charles Riegel's angioplasty had not been manufactured in accordance with the PMA-approved standards

– we agree with the district court that this claim was not preempted, but that no genuine issue of material fact existed, and thus affirm the district court's summary judgment dismissal of that claim as well."); *Brooks*, 273 F.3d at 789 ("Brooks is correct in her assertion that a claim of failure to comply with FDA regulations is not preempted by the MDA, since such a state claim imposes no requirement 'different from, or in addition to' any federal requirement," but her claim for "negligence per se" must be dismissed because she "presented no evidence that Howmedica violated federal regulations or refused to add warnings drafted by the FDA, changed FDA-approved labels, failed to meet regular reporting requirements, failed to report a known hazard to the FDA, or failed to comply with federal law in any other respect"). Indeed, in those cases where the courts concluded that all of the plaintiffs' claims were preempted, the courts were careful to note that the plaintiffs did *not* assert that the defendant had failed to comply with FDA requirements. *See Horn*, 376 F.3d at 179 ("Horn has not asserted that [the defendant] has in any way failed to conform with the FDA requirements prescribed by its PMA – nor that it deviated from, or violated, any of the FDA's federal statutes or regulations"); *Papike*, 107 F.3d at 743 ("[the plaintiff] does not allege negligent manufacture").

To be fair, two courts have concluded that breach of express warranty claims are *not* automatically preempted. In *Riegel*, however, there was no discussion of why this claim was not preempted, and the claim was dismissed after discovery revealed that the instructions for the medical device "clearly disclaimed any express warranty." *Riegel*, 451 F.3d at 108. In *Mitchell*, the court did explain that a state-law claim for breach of express warranty is not preempted because "[express] warranties arise from the representations of the parties and are made as the basis of the bargain between them. A state judgment based on the breach of an express representation by one of the

parties does not necessarily interfere with the operation of the PMA, and therefore we cannot say that such a cause of action is preempted." *Mitchell*, 126 F.3d at 915. The analysis went no further, however, because the plaintiffs "never specified whether their claim was based on an express or an implied warranty," and did not "ever state[] the nature of any express warranty;" accordingly, the claim was dismissed on summary judgment. *Id.* In any event, neither *Mitchell* nor *Riegel* provides sufficient reason to ignore the Sixth Circuit's conclusion in *Kemp* that "the MDA preempted [the] plaintiffs' . . . claims for . . . breach of express and implied warranties." *Kemp*, 231 F.3d at 219.[12]

In sum, the only claims stated by Howard and Burgess that are not preempted by §360k(a) of the MDA are their claims of negligence per se, where they assert that Sulzer failed to conform with the FDA requirements established for the NK-II through the PMA process. Their other claims for design defect, manufacturing defect, defective marketing, failure to warn, negligence, breach of

[12] It is also worth noting that Howard states his breach of express warranty claims are "based upon the statements contained in the package inserts and other written materials associated with the [NK-II]," and not any independent representations between the parties. Response brief at 27 (docket no. 9). The written materials Howard points to, of course, are reviewed as part of the FDA's PMA process; success on this claim would necessarily create conflict with the FDA's requirements. Burgess does not provide any explanation for the basis of his claim of breach of express warranty.

implied warranty, breach of express warranty, and deceit are all preempted.[13]

III. Remaining Evidentiary Issues.

As noted above, the *Gomez* court permitted a plaintiff to pursue a claim that the defendant failed to manufacture a medical device in accordance with FDA specifications, and further concluded that the plaintiff had adduced enough evidence in support of this claim to survive a Rule 50 motion for judgment as a matter of law. The latter conclusion is unusual to the point of being unique; most plaintiffs who were allowed to pursue similar non-preempted claims, such as the plaintiffs in *Martin*, *Kemp*, *Riegel*, and *Brooks*, find themselves unable to adduce sufficient evidence of the defendant's failure to adhere to PMA requirements to survive summary judgment.

Sulzer insists the more common result will occur in this case, and further argues that enough

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[13] There are three other "claims" stated by Howard and Burgess. Howard's "claim" for medical monitoring is actually a request for injunctive relief, entitlement to which depends on the success of a substantive claim. Thus, this claim necessarily rises and falls with Howard's other claims. Similarly, Howard's and Burgess's spouses' claims for loss of consortium are derivative, so they are preempted to the extent the underlying substantive claims are preempted.

Finally, with his claim of fraud, Burgess contends that, when Sulzer identified certain lots of NK-II implants it had manufactured improperly, and provided settlement benefits to recipients of these implants pursuant to the MDL Settlement Agreement, Sulzer knew there were *additional* NK-II implants that were improperly manufactured (such as Burgess's), and Sulzer purposefully excluded recipients of these implants from the settlement. This claim is clearly a collateral attack on this Court's Final Fairness Hearing, at which time the Court heard extensive evidence regarding the efforts that both plaintiffs and defendants undertook to identify all persons who were proper members of the settlement class.

Indeed, Burgess's fraud allegations fail not only for lack of specificity, but also for lack of any basis in reality – it is pure fiction (and insulting) for Burgess to allege that "the members of [the settlement class] were selected wholly upon information supplied by defendants as to which manufacturing lots of the device contained the defective product." Amended complaint at ¶24. Two days' worth of testimony at the Final Fairness Hearing convinced this Court otherwise. The time for appealing the Court's determinations regarding class membership is long past, and Burgess may not collaterally attack this Court's conclusions in this regard in his current case.

discovery has already occurred in the MDL to allow the Court to enter judgment *now* on Howard's and Burgess's claims for negligence per se. That is, Sulzer insists the state of the evidentiary record shows already that there is no issue of material fact and it is entitled to judgment as a matter of law on Burgess's and Howard's claims of negligence per se.

There is substantial strength to Sulzer's argument. For example, one position Howard has taken to support his claim of negligence per se is that, like those plaintiffs whom this Court certified as members of the MDL settlement class, Howard's NK-II underwent machining *after* porous coating, thereby allowing machine oil to remain on the surface of the finished implant (which caused the implant not to bond properly to the bone). In response, Sulzer notes that: (1) extensive discovery by all parties leading up to the MDL Settlement Agreement identified all those implants where machining occurred *after* porous coating, and Howard's implant was not among them; and (2) specific manufacturing records reflect that Howard's implant was machined *before* porous coating. Having reviewed all of this evidence carefully during the Final Fairness Hearing, and having heard from MDL discovery counsel regarding their extensive efforts at identifying which implants were defective and why, it is hard for the undersigned to imagine that additional discovery will provide Howard with evidence to support his theory that his implant was, in fact, machined after porous coating.

Another position Howard takes to support his claim of negligence per se is to note that he had his implant tested by a chemical laboratory, and the results show the implant had on it traces of chemicals "normally associated with mineral [machine] oil." Howard avers that "it is axiomatic that such residues should not be remain [sic] on the implanted device," and "a manufacturing process that fails to remove such residue would materially deviate from any FDA requirements, because such

residue should never be present on such implants at the time of implantation." Howard affidavit at ¶¶7, 9.[14] This analysis appears faulty in two respects. First, the Court heard evidence at the Final Fairness Hearing that it is impossible to remove *all* of the machine oil from an implant.[15] Thus, it is not "axiomatic" that, because Howard's implant may test positive for machine oil residue, Sulzer must have deviated from FDA manufacturing requirements. Second, Howard suggests that the FDA requirements applicable to the NK-II must include cleaning processes and quality controls with mandated maximum levels of residue, and he alleges these maximums were exceeded in his case. It is at least as likely, however, that, while the FDA requirements mandate certain cleaning processes and quality controls, those requirements do not mandate specific, maximum residue levels. That is, the cleaning procedures are mandated, but not the precise results. If so, Howard's claim for negligence per se will fail so long as Sulzer followed the required cleaning processes and quality controls, regardless of how residue-free those manufacturing steps actually left his NK-II. And Sulzer has already adduced evidence that it followed all the required cleaning processes and quality control steps when it manufactured Howard's implant.

Ultimately, however, the Court concludes it would be premature to enter judgment on Howard's and Burgess's remaining claims at this juncture. Howard and Burgess argue they should

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[14] Howard is himself an orthopedic surgeon who frequently implanted in others Sulzer's NK-II.

[15] *See* case no. 01-CV-9000, master docket no. 327, exhibit 18, ¶11 (affidavit of Dr. Toby Hayes) ("The use of machining and cooling oils in manufacturing operations results in some measurable residual oil on all orthopaedic implants, even with the use of rigorous cleaning procedures. * * * With monitoring, these levels can be maintained below those known in the industry to be safe and effective."); exhibit 25, ¶9 (affidavit of Dr. William Maloney) ("Although orthopedic implants commonly contain some amount of [oil] residue, the level of residue in a number of these cases exceeded that which would be normally expected.").

be allowed to pursue their own discovery to test the veracity of Sulzer's evidentiary submissions, and also to see if they can uncover some other deviation from FDA requirements by Sulzer that caused their particular NK-II implants not to work as intended. The current state of the evidence suggests this may be an uphill battle, but it is theirs to choose to fight. If Sulzer is correct, it may reassert its argument that it is entitled to judgment on Howard's and Burgess's negligence per se claims in the context of Rule 56. Howard and Burgess must each be allowed an opportunity to conduct discovery to uncover factual support for their single remaining claim.

Under separate order, the Court will schedule a telephonic status hearing with the parties to set new discovery and other deadlines.

IT IS SO ORDERED.

/s/ Kathleen M. O'Malley
KATHLEEN McDONALD O'MALLEY
UNITED STATES DISTRICT JUDGE

DATED: October 3, 2006